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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,626	12/18/2000	Satoshi Nakagawa	249-125	2229

7590 07/22/2003

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/22/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,626

Applicant(s)

NAKAGAWA ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 19, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-110 is/are pending in the application.
- 4a) Of the above claim(s) 69-78 and 84-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 69-110 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' arguments in Paper No. 13, filed May 19, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title and drawings have been accepted.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 79-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. This rejection is maintained with respect to Claims 79-82, as recited in the previous office action Paper No. 11, mailed November 19, 2002.
6. Specific to claims 79 and 81 Step (iii), 80 and 82 Step (iv), the phrase "coincident with or analogous to" causes the claims to be vague and indefinite because it is not clear what criteria are being applied to judge whether a sequence is "coincident with or analogous to" a target sequence? Also, this phrase is used to describe the relationships of target sequence and target structure motif to their respective sequences determined by the comparator. Are the same criteria being applied to a sequence for it to be considered as "coincident with or analogous to" a target sequence or target structure?

7. Applicants argue that the phrase “coincident with or analogous to” in regard sequence search is well known in the art because one of ordinary skill in the art would equate the phrase to mean the e-value is e^{-10} or less when FASTA is used for a homology search. A Pearson et al. reference is provided not as prior art but only to disclose that Applicants’ pointed to citation does not help resolve the issue of claims 79-82 being vague and indefinite. It is acknowledged that Pearson et al. discloses “the locations of the initial regions, their respective scores, and a “joining” penalty (analogous to a gap penalty), FASTA calculates an optimal alignment of initial regions as a combination of compatible regions with maximal score” (page 2444, column 2, lines 30-32). However, the Examiner has not been able to find the phrase “coincident with or analogous to” as directed to mean the e-value is e^{-10} or less when FASTA is used for a homology search in the Pearson et al. FASTA reference.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

8. Claims 79-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which as not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. This rejection is maintained with respect to Claims 79-83, as recited in the previous office action Paper No. 11, mailed November 19, 2002.

10. Applicants’ arguments directed to the lack of enablement in scope for method and system for identifying a target sequence or a target structure motif derived from the genus *Brevibacterium* or other specific microorganisms as listed in the preamble of claim 79 and thereof, have been considered and found to be unpersuasive.

11. It is acknowledged that Applicants present arguments that state “microorganisms belonging to the genus *Corynebacterium* have a high percentage homology in chromosomal DNA”, therefore, the high similarity among the microorganisms support the scope of the claimed subject matter in claims 79-83, in its entirety. The said arguments have been fully considered and found to be unpersuasive because the cited high percentage homology of chromosomal DNA does not help Applicants overcome the fact that the claimed subject matter relies on an indirect method of comparing sequences to the GenBank database sequences. Since this is not a direct comparison to the GenBank database sequences, it would be speculative at best for one skilled in the art to be able to use the method and system disclosed in this instant case to identify a sequence that is homologous to a target sequence, which is 30% identity to a *Corynebacterium glutamicum* sequence in the GenBank database. The method and system of this instant case rely on data that are few steps away from the actual sequence being used for identifying sequences. Therefore, it is unreasonable to expect one skilled in the art to use the information disclosed to make and use the inventions to conclusively predict query sequence identity without undue experimentation.

12. Applicants’ arguments directed to the lack of enablement in scope for method and system for determining a function of a polypeptide encoded by a polynucleotide having a target nucleotide sequence have been considered and found to be unpersuasive.

13. It is acknowledged that Applicants argue that function can be inferred for proteins as long as they have at least 30% identity and similarity, the query sequences are similar to targets sequences which are known to be one of gene groups forming a cluster on the chromosomal DNA, or sequence similarities occur in a domain of an active site. The said arguments and

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cited support have been considered and found to be unpersuasive because they do not address the strong evidence within the art that refutes the reliability of the use homology search results to confer function to a target sequence (Paper 11, page 5, lines 16-22 to page 6, lines 1-4). Further, the cited NCBI document only provides a tutorial on how various BLAST parameters are determined and interpreted, but does not address the unreliability of the use homology search results to confer function to a target sequence.

14. "When analyzing a database search, it may be unclear how much functional annotation can be legitimately inherited by a query sequence" (page 472, column 2, lines 4-7). Specific to the argument of function can be assigned via sequence similarities occur in a domain of an active site, "the best hit in a database search is a match to a single domain or module, it is unlikely that the function annotation can be propagated from the parent protein to the query sequence (Attwood, page 472, column 2, lines 18-21).

15. Therefore, it is suggested by Attwood that assigning function to proteins sequences through sequences search is unreliable whether the parameters used to confer gene function is identity, similarity, or homology.

CLAIM REJECTIONS - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

17. A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim are 79-83 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mewes et al. (1998).

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19. This rejection is maintained with respect to Claims 79-83, as recited in the previous office action Paper No. 11, mailed November 19, 2002.

20. Applicants argue that the cited prior art fails to teach the limitations, SEQ ID NOs. 1 to 3501 or SEQ ID NOs. 3502 to 7001, which have been considered as non-functional descriptive material. Further, the claimed system and methods of using the said system provide more than a means of data storage for non-functional descriptive material because they provide a “user input device, ...comparator, and output device.” The said arguments are acknowledged and found to be unpersuasive.

21. It is acknowledged that claimed subject matter comprises “user input device, ...comparator, and output device.” However, these limitations merely store the non-functional descriptive material, SEQ ID NOs. 1 to 3501 or SEQ ID NOs. 3502 to 7001, so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Further, the limitation of the comparator merely used for comparing the said non-functional descriptive material and does not impart functionality either to the data as so structured, or to the computer.

CONCLUSION

22. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

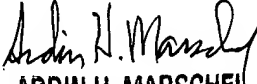
24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
7/21/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER